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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/825,757 | 04/16/2004 | Jeffrey M. Linnen | GP146-04.UT | 8545 |

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| EXAMINER | |
|---|---|
| SALMON, KATHERINE D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 03/25/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| **Advisory Action Before the Filing of an Appeal Brief** | **Application No.** 10/825,757 | **Applicant(s)** LINNEN ET AL. | |
|---|---|---|---|
| | **Examiner** KATHERINE SALMON | **Art Unit** 1634 | |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 06 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 35 USC 102(e).
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *116 and 124-130*.
   Claim(s) withdrawn from consideration: *131 and 139-144*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Juliet C Switzer/
Primary Examiner, Art Unit 1634

Continuation of 11: NOTE: The reply traverses the 35 USC 103(a) rejection. A summary of the arguments is presented below with response to arguments following.

The reply asserts that applicants have previously pointed out that other detection probes were designed and tested that overlapped with but were not contained within the target binding portion of the claimed probes (p. 6 last paragraph). The reply points to the probes identified by SEQ ID NO. 44 and 45 wherein these probes only share 6 contiguous bases in common with SEQ ID No. 3 (p. 6 last paragraph). The reply asserts that while the specification states that it is possible that these probes could be optimized to detect target amplicon, optimization would involve changing the probe sequences, most logically by tiling toward a sequence shown to exhibit the desired hybridization characteristics (p. 6 last paragraph and p. 7 1st paragraph). The reply asserts that therefore it has been shown that the overlapping probes do not perform as well as the claimed probes (p. 7 1st paragraph).

These arguments have been fully reviewed but have not been found persuasive.

As argued in the Final rejection (1/08/2009) on p. 13-14, applicant is pointing to probes in the specification which indicates "could detectably hybridize to target amplicon derived from the transcript in an optimized assay, or that the target binding portions of these probes could be incorporated into linear detection probes that would detectably hybridize to the target amplicon" (p. 58 lines 5-10 of instant specification). The reply asserts that the only way to optimize these probes would be to change the probe sequence by tiling a sequence to the desired hybridization characteristic of being at least 18 mer of SEQ ID No. 3. However, the instant specification discloses that hybridization to the target could be done obtained "an optimized assay". It is known in the art that one of the ways to effect the hybridization between a probe and a target is the assay conditions of the hybridization assay. Peiris et al. (US Patent application 2005/0009009 used in the 35 USC 103(a) rejection of record) teaches that stringent conditions includes any hybridization conditions which are well known to those skilled in the art (p. 3 paragraph 26). Peiris et al. further teaches two nonlimiting examples of stringent hybridization conditions which are run at different temperatures. Therefore although the reply asserts the only way to optimize is to change the probe sequences, the ordinary artisan would be able to affect hybridization by a number of factors such as the running temperature of the hybridization assay and the concentration of reagents used in the assay. Therefore optimization of these probes in a hybridization assay would include a number of conditions which the ordinary artisan can change in a routine experimentation which would effect the hybridization of the probes to the target.

Further the assertion that the instant specification provides examples which disclose unexpected results is not commensurate in scope with the claimed invention. The claimed invention is drawn to probes which comprises at least 18 nucleotides of SEQ ID No. 3, but can comprise any number of nucleotides flanking that region. The reply has not provided any secondary evidence or argument that any probe with 18 contiguous nucleotides of SEQ ID No. 3 will hybridize to the target whereas other probes do not hybridize to the target, only that in two examples in the instant specification the probe with 18 nucleotides in common with SEQ ID No. 3 perform better in a particular optimized assay. The claims, however, are not drawn to any degree of hybridization. As such the 35 USC 103(a) rejection which states that it would be obvious to design any probes to detect SARS-CoV using the constraints of Peiris et al. including the claimed probes is maintained.